



General

Guideline Title

Management of venous leg ulcers: clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum

Bibliographic Source(s)

O'Donnell TF Jr, Passman MA, Marston WA, Ennis WJ, Dalsing M, Kistner RL, Lurie F, Henke PK, Gloviczki ML, Eklaiff BG, Stoughton J, Raju S, Shortell CK, Raffetto JD, Partsch H, Pounds LC, Cummings ME, Gillespie DL, McLafferty RB, Murad MH, Wakefield TW, Gloviczki P, Society for Vascular Surgery, American Venous Forum. Management of venous leg ulcers: clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. J Vasc Surg. 2014 Aug;60(2 Suppl):3S-59S. [547 references] [PubMed](#)

Guideline Status

This the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Regulatory Alert

FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- December 14, 2016 – General anesthetic and sedation drugs : The U.S. Food and Drug Administration (FDA) is warning that repeated or lengthy use of general anesthetic and sedation drugs during surgeries or procedures in children younger than 3 years or in pregnant women during their third trimester may affect the development of children's brains. Consistent with animal studies, recent human studies suggest that a single, relatively short exposure to general anesthetic and sedation drugs in infants or toddlers is unlikely to have negative effects on behavior or learning. However, further research is needed to fully characterize how early life anesthetic exposure affects children's brain development.

Recommendations

Major Recommendations

Definitions of the strength of the recommendations (Grade 1 or 2) and quality of the evidence (Level A–C) are provided at the end of the "Major Recommendations" field.

Definition Venous Leg Ulcer

1. The Committee suggests use of a standard definition of venous ulcer as an open skin lesion of the leg or foot that occurs in an area affected by venous hypertension. [Best Practice]

Venous Anatomy and Pathophysiology

1. The Committee recommends use of the International Consensus Committee on Venous Anatomical Terminology for standardized venous anatomy nomenclature. [Best Practice]
2. The Committee recommends a basic practical knowledge of venous physiology and venous leg ulcer pathophysiology for all practitioners caring for venous leg ulcers. [Best Practice]

Clinical Evaluation

1. The Committee recommends that for all patients with suspected leg ulcers fitting the definition of venous leg ulcer, clinical evaluation for evidence of chronic venous disease be performed. [Best Practice]
2. The Committee recommends identification of medical conditions that affect ulcer healing and other nonvenous causes of ulcers. [Best Practice]
3. The Committee recommends serial venous leg ulcer wound measurement and documentation. [Best Practice]
4. The Committee suggests against routine culture of venous leg ulcers and only to obtain wound culture specimens when clinical evidence of infection is present. [Grade - 2; Level of Evidence - C]
5. The Committee recommends wound biopsy for leg ulcers that do not improve with standard wound and compression therapy after 4 to 6 weeks of treatment and for all ulcers with atypical features. [Grade - 1; Level of Evidence - C]
6. The Committee suggests laboratory evaluation for thrombophilia for patients with a history of recurrent venous thrombosis and chronic recurrent venous leg ulcers. [Grade - 2; Level of Evidence - C]
7. The Committee recommends arterial pulse examination and measurement of ankle-brachial index on all patients with venous leg ulcer. [Grade - 1; Level of Evidence - B]
8. The Committee suggests against routine microcirculation assessment of venous leg ulcers but suggest selective consideration as an adjunctive assessment for monitoring of advanced wound therapy. [Grade - 2; Level of Evidence - C]
9. The Committee recommends comprehensive venous duplex ultrasound examination of the lower extremity in all patients with suspected venous leg ulcer. [Grade - 1; Level of Evidence - B]
10. The Committee suggests selective use of venous plethysmography in the evaluation of patients with suspected venous leg ulcer if venous duplex ultrasound does not provide definitive diagnostic information. [Grade - 2; Level of Evidence - B]
11. The Committee suggests selective computed tomography venography, magnetic resonance venography, contrast venography, and/or intravascular ultrasound in patients with suspected venous leg ulceration if additional advanced venous diagnosis is required for thrombotic or nonthrombotic iliac vein obstruction or for operative planning before open or endovenous interventions. [Grade - 2; Level of Evidence - C]
12. The Committee recommends that all patients with venous leg ulcer be classified on the basis of venous disease classification assessment, including clinical, etiology, anatomy, and pathophysiology (CEAP) classification, revised Venous Clinical Severity Score, and venous disease-specific quality of life assessment. [Best Practice]
13. The Committee recommends venous procedural outcome assessment including reporting of anatomic success, venous hemodynamic success, procedure-related minor and major complications, and impact on venous leg ulcer healing. [Best Practice]

Wound Care

1. The Committee suggests that venous leg ulcers be cleansed initially and at each dressing change with a neutral, nonirritating, nontoxic solution, performed with a minimum of chemical or mechanical trauma. [Grade - 2; Level of Evidence - C]
2. The Committee recommends that venous leg ulcers receive thorough débridement at their initial evaluation to remove obvious necrotic tissue, excessive bacterial burden, and cellular burden of dead and senescent cells. [Grade - 1; Level of Evidence - B] The Committee suggests that additional maintenance débridement be performed to maintain the appearance and readiness of the wound bed for healing. [Grade - 2; Level of Evidence - B] The Committee suggests that the health care provider choose from a number of débridement methods, including sharp, enzymatic, mechanical, biologic, and autolytic. More than one débridement method may be appropriate. [Grade - 2; Level of Evidence - B]
3. The Committee recommends that local anesthesia (topical or local injection) be administered to minimize discomfort associated with surgical venous leg ulcer débridement. In selected cases, regional block or general anesthesia may be required. [Grade - 1; Level of Evidence - B]
4. The Committee recommends that surgical débridement be performed for venous leg ulcers with slough, nonviable tissue, or eschar. Serial

- wound assessment is important in determining the need for repeated débridement. [Grade - 1; Level of Evidence - B]
5. The Committee suggests hydrosurgical débridement as an alternative to standard surgical débridement of venous leg ulcers. [Grade - 2; Level of Evidence - B]
 6. The Committee suggests against ultrasonic débridement over surgical débridement in the treatment of venous leg ulcers. [Grade - 2; Level of Evidence - C]
 7. The Committee suggests enzymatic débridement of venous leg ulcers when no clinician trained in surgical débridement is available to débride the wound. [Grade - 2; Level of Evidence - C] The Committee does not suggest enzymatic débridement over surgical débridement. [Grade - 2; Level of Evidence - C]
 8. The Committee suggests that larval therapy for venous leg ulcers can be used as an alternative to surgical débridement. [Grade - 2; Level of Evidence - B]
 9. The Committee recommends that cellulitis (inflammation and infection of the skin and subcutaneous tissue) surrounding the venous leg ulcer be treated with systemic gram-positive antibiotics. [Grade - 1; Level of Evidence - B]
 10. The Committee suggests against systemic antimicrobial treatment of venous leg ulcer colonization or biofilm without clinical evidence of infection. [Grade - 2; Level of Evidence - C]
 11. The Committee suggests that venous leg ulcers with $>1 \times 10^6$ CFU/g of tissue and clinical evidence of infection be treated with antimicrobial therapy. [Grade - 2; Level of Evidence - C] The Committee suggests antimicrobial therapy for virulent or difficult to eradicate bacteria (such as beta-hemolytic streptococci, pseudomonas, and resistant staphylococcal species) at lower levels of colony-forming units per gram of tissue. [Grade - 2; Level of Evidence - C] The Committee suggests a combination of mechanical disruption and antibiotic therapy as most likely to be successful in eradicating venous leg ulcer infection. [Grade - 2; Level of Evidence - C]
 12. The Committee recommends that venous leg ulcers with clinical evidence of infection be treated with systemic antibiotics guided by sensitivities performed on wound culture. [Grade - 1; Level of Evidence - C] Oral antibiotics are preferred initially, and the duration of antibiotic therapy should be limited to 2 weeks unless persistent evidence of wound infection is present. [Grade - 1; Level of Evidence - C]
 13. The Committee suggests against use of topical antimicrobial agents for the treatment of infected venous leg ulcers. [Grade - 2; Level of Evidence - C]
 14. The Committee suggests applying a topical dressing that will manage venous leg ulcer exudate and maintain a moist, warm wound bed. [Grade - 2; Level of Evidence - C] The Committee suggests selection of a primary wound dressing that will absorb wound exudate produced by the ulcer (alginates, foams) and protect the periulcer skin. [Grade - 2; Level of Evidence - B]
 15. The Committee recommends against the routine use of topical antimicrobial-containing dressings in the treatment of noninfected venous leg ulcers. [Grade - 2; Level of Evidence - A]
 16. The Committee suggests application of skin lubricants underneath compression to reduce dermatitis that commonly affects periulcer skin. [Grade - 2; Level of Evidence - C] In severe cases of dermatitis associated with venous leg ulcers, the Committee suggests topical steroids to reduce the development of secondary ulcerations and to reduce the symptoms of dermatitis. [Grade - 2; Level of Evidence - C]
 17. The Committee suggests against use of anti-inflammatory therapies for the treatment of venous leg ulcers. [Grade - 2; Level of Evidence - C]
 18. The Committee recommends adjuvant wound therapy options for venous leg ulcers that fail to demonstrate improvement after a minimum of 4 to 6 weeks of standard wound therapy. [Grade - 1; Level of Evidence - B]
 19. The Committee suggests against split-thickness skin grafting as primary therapy in treatment of venous leg ulcers. [Grade - 2; Level of Evidence - B] The Committee suggests split-thickness skin grafting with continued compression for selected large venous leg ulcers that have failed to show signs of healing with standard care for 4 to 6 weeks. [Grade - 2; Level of Evidence - B]
 20. The Committee suggests the use of cultured allogeneic bilayer skin replacements (with both epidermal and dermal layers) to increase the chances for healing in patients with difficult to heal venous leg ulcers in addition to compression therapy in patients who have failed to show signs of healing after standard therapy for 4 to 6 weeks. [Grade - 2; Level of Evidence - A]
 21. The Committee suggests a therapeutic trial of appropriate compression and wound bed moisture control before application of cellular therapy. [Grade - 2; Level of Evidence - C] The Committee recommends that adequate wound bed preparation, including complete removal of slough, debris, and any necrotic tissue, be completed before the application of a bilayered cellular graft. [Grade - 1; Level of Evidence - C] The Committee recommends additional evaluation and management of increased bioburden levels before the application of cellular therapy. [Grade - 1; Level of Evidence - C]
 22. The Committee suggests reapplication of cellular therapy as long as the venous leg ulcer continues to respond on the basis of wound documentation. [Grade - 2; Level of Evidence - C]
 23. The Committee suggests the use of a porcine small intestinal submucosal tissue construct in addition to compression therapy for the treatment of venous leg ulcers that have failed to show signs of healing after standard therapy for 4 to 6 weeks. [Grade - 2; Level of Evidence - B]
 24. The Committee suggests against routine primary use of negative pressure wound therapy for venous leg ulcers. [Grade - 2; Level of Evidence - C]

25. The Committee suggests against electrical stimulation therapy for venous leg ulcers. [Grade - 2; Level of Evidence - C]
26. The Committee suggests against routine ultrasound therapy for venous leg ulcers. [Grade - 2; Level of Evidence - B]

Compression

1. In a patient with a venous leg ulcer, the Committee recommends compression therapy over no compression therapy to increase venous leg ulcer healing rate. [Grade - 1; Level of Evidence - A]
2. In a patient with a healed venous leg ulcer, the Committee suggests compression therapy to decrease the risk of ulcer recurrence. [Grade - 2; Level of Evidence - B]
3. The Committee suggests the use of multicomponent compression bandage over single-component bandages for the treatment of venous leg ulcers. [Grade - 2; Level of Evidence - B]
4. In a patient with a venous leg ulcer and underlying arterial disease, the Committee does not suggest compression bandages or stockings if the ankle-brachial index is 0.5 or less or if absolute ankle pressure is less than 60 mm Hg. [Grade - 2; Level of Evidence - C]
5. The Committee suggests use of intermittent pneumatic compression when other compression options are not available, cannot be used, or have failed to aid in venous leg ulcer healing after prolonged compression therapy. [Grade - 2; Level of Evidence - C]

Operative/Endovascular Management

1. In a patient with a venous leg ulcer (C6) and incompetent superficial veins that have axial reflux directed to the bed of the ulcer, the Committee suggests ablation of the incompetent veins in addition to standard compressive therapy to improve ulcer healing. [Grade - 2; Level of Evidence - C]
2. In a patient with a venous leg ulcer (C6) and incompetent superficial veins that have axial reflux directed to the bed of the ulcer, the Committee recommends ablation of the incompetent veins in addition to standard compressive therapy to prevent recurrence. [Grade - 1; Level of Evidence - B]
3. In a patient with a healed venous leg ulcer (C5) and incompetent superficial veins that have axial reflux directed to the bed of the ulcer, the Committee recommends ablation of the incompetent veins in addition to standard compressive therapy to prevent recurrence. [Grade - 1; Level of Evidence - C]
4. In a patient with skin changes at risk for venous leg ulcer (C4b) and incompetent superficial veins that have axial reflux directed to the bed of the affected skin, the Committee suggests ablation of the incompetent superficial veins in addition to standard compressive therapy to prevent ulceration. [Grade - 2; Level of Evidence - C]
5. In a patient with a venous leg ulcer (C6) and incompetent superficial veins that have reflux to the ulcer bed in addition to pathologic perforating veins (outward flow of >500 ms duration, with a diameter of >3.5 mm) located beneath or associated with the ulcer bed, the Committee suggests ablation of both the incompetent superficial veins and perforator veins in addition to standard compressive therapy to aid in ulcer healing and to prevent recurrence. [Grade - 2; Level of Evidence - C]
6. In a patient with skin changes at risk for venous leg ulcer (C4b) or healed venous ulcer (C5) and incompetent superficial veins that have reflux to the ulcer bed in addition to pathologic perforating veins (outward flow of >500 ms duration, with a diameter of >3.5 mm) located beneath or associated with the healed ulcer bed, the Committee suggests ablation of the incompetent superficial veins to prevent the development or recurrence of a venous leg ulcer. [Grade - 2; Level of Evidence - C] Treatment of the incompetent perforating veins can be performed simultaneously with correction of axial reflux or can be staged with re-evaluation of perforator veins for persistent incompetence after correction of axial reflux. [Grade - 2; Level of Evidence - C]
7. In a patient with isolated pathologic perforator veins (outward flow of >500 ms duration, with a diameter of >3.5 mm) located beneath or associated with the healed (C5) or active ulcer (C6) bed regardless of the status of the deep veins, the Committee suggests ablation of the “pathologic” perforating veins in addition to standard compression therapy to aid in venous ulcer healing and to prevent recurrence. [Grade - 2; Level of Evidence - C]
8. For those patients who would benefit from pathologic perforator vein ablation, the Committee recommends treatment by percutaneous techniques that include ultrasound-guided sclerotherapy or endovenous thermal ablation (radiofrequency or laser) over open venous perforator surgery to eliminate the need for incisions in areas of compromised skin. [Grade - 1; Level of Evidence - C]
9. In a patient with infrainguinal deep venous obstruction and skin changes at risk for venous leg ulcer (C4b), healed venous leg ulcer (C5), or active venous leg ulcer (C6), the Committee suggests autogenous venous bypass or endophlebectomy in addition to standard compression therapy to aid in venous ulcer healing and to prevent recurrence. [Grade - 2; Level of Evidence - C]
10. In a patient with infrainguinal deep venous reflux and skin changes at risk for venous leg ulcer (C4b), healed venous leg ulcer (C5), or active venous leg ulcer (C6), the Committee suggests against deep vein ligation of the femoral or popliteal veins as a routine treatment. [Grade - 2; Level of Evidence - C]
11. In a patient with infrainguinal deep venous reflux and skin changes at risk for venous leg ulcer (C4b), healed venous leg ulcer (C5), or active venous leg ulcer (C6), the Committee suggests individual valve repair for those who have axial reflux with structurally preserved deep

- venous valves in addition to standard compression therapy to aid in venous ulcer healing and to prevent recurrence. [Grade - 2; Level of Evidence - C]
12. In a patient with infrainguinal deep venous reflux and skin changes at risk for venous leg ulcer (C4b), healed venous leg ulcer (C5), or active venous leg ulcer (C6), the Committee suggests valve transposition or transplantation for those with absence of structurally preserved axial deep venous valves when competent outflow venous pathways are anatomically appropriate for surgical anastomosis in addition to standard compression therapy to aid in venous leg ulcer healing and to prevent recurrence. [Grade - 2; Level of Evidence - C]
 13. In a patient with infrainguinal deep venous reflux and skin changes at risk for venous leg ulcer (C4b), healed venous leg ulcer (C5), or active venous leg ulcer (C6), the Committee suggests consideration of autogenous valve substitutes by surgeons experienced in these techniques to facilitate ulcer healing and to prevent recurrence in those with no other option available in addition to standard compression therapy to aid in venous ulcer healing and to prevent recurrence. [Grade - 2; Level of Evidence - C]
 14. In a patient with inferior vena cava or iliac vein chronic total occlusion or severe stenosis, with or without lower extremity deep venous reflux disease, that is associated with skin changes at risk for venous leg ulcer (C4b), healed venous leg ulcer (C5), or active venous leg ulcer (C6), the Committee recommends venous angioplasty and stent recanalization in addition to standard compression therapy to aid in venous ulcer healing and to prevent recurrence. [Grade - 1; Level of Evidence - C]
 15. In a patient with inferior vena cava or iliac vein chronic occlusion or severe stenosis, with or without lower extremity deep venous reflux disease, that is associated with a recalcitrant venous leg ulcer and failed endovascular treatment, the Committee suggests open surgical bypass with use of an externally supported expanded polytetrafluoroethylene graft in addition to standard compression therapy to aid in venous leg ulcer healing and to prevent recurrence. [Grade - 2; Level of Evidence - C]
 16. In a patient with unilateral iliofemoral venous occlusion/severe stenosis with recalcitrant venous leg ulcer for whom attempts at endovascular reconstruction have failed, the Committee suggests open surgical bypass with use of saphenous vein as a cross-pubic bypass (Palma procedure) to aid in venous ulcer healing and to prevent recurrence. A synthetic graft is an alternative in the absence of autogenous tissue. [Grade - 2; Level of Evidence - C]
 17. For those patients who would benefit from an open venous bypass, the Committee suggests the addition of an adjunctive arteriovenous fistula (4-6 mm in size) as an adjunct to improve inflow into autologous or prosthetic crossover bypasses when the inflow is judged to be poor to aid in venous leg ulcer healing and to prevent recurrence. [Grade - 2; Level of Evidence - C]

Ancillary Measures

1. The Committee recommends that nutrition assessment be performed in any patient with a venous leg ulcer who has evidence of malnutrition and that nutritional supplementation be provided if malnutrition is identified. [Best Practice]
2. For long-standing or large venous leg ulcer, the Committee recommends treatment with either pentoxifylline or micronized purified flavonoid fraction used in combination with compression therapy. [Grade - 1; Level of Evidence - B]
3. The Committee suggests supervised active exercise to improve muscle pump function and to reduce pain and edema in patients with venous leg ulcers. [Grade - 2; Level of Evidence - B]
4. The Committee suggests against adjunctive lymphatic drainage for healing of the chronic venous leg ulcers. [Grade - 2; Level of Evidence - C]
5. The Committee suggests balneotherapy to improve skin trophic changes and quality of life in patients with advanced venous disease. [Grade - 2; Level of Evidence - B]
6. The Committee suggests against use of ultraviolet light for the treatment of venous leg ulcers. [Grade - 2; Level of Evidence - C]

Primary Prevention

1. In patients with clinical CEAP C3-4 disease due to primary valvular reflux, the Committee recommends compression, 20 to 30 mm Hg, knee or thigh high. [Grade - 2; Level of Evidence - C]
2. In patients with clinical CEAP C1-4 disease related to prior deep venous thrombosis (DVT), the Committee recommends compression, 30 to 40 mm Hg, knee or thigh high. [Grade - 1; Level of Evidence - B]
3. As post-thrombotic syndrome is a common preceding event for venous leg ulcers, the Committee recommends current evidence-based therapies for acute DVT treatment. [Grade - 1; Level of Evidence - B] The Committee suggests use of low-molecular-weight heparin over vitamin K antagonist therapy of 3-month duration to decrease post-thrombotic syndrome. [Grade - 2; Level of Evidence - B] The Committee suggests catheter-directed thrombolysis in patients with low bleeding risk with iliofemoral DVT of duration <14 days. [Grade - 2; Level of Evidence - B]
4. In patients with C1-4 disease, the Committee suggests patient and family education, regular exercise, leg elevation when at rest, careful skin care, weight control, and appropriately fitting foot wear. [Best Practice]
5. In patients with asymptomatic C1-2 disease from either primary or secondary causes, the Committee suggests against prophylactic interventional therapies to prevent venous leg ulcer. [Grade - 2; Level of Evidence - C]

Definitions

Grading of Recommendations Assessment, Development and Evaluation (GRADE) Recommendations Based on Level of Evidence

Grade	Description of Recommendation	Benefit vs. Risk	Methodologic Quality of Supporting Evidence	Implications
1A	Strong recommendation, high-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	Randomized controlled trials (RCTs) without important limitations or overwhelming evidence from observational studies	Strong recommendation, can apply to most patients in most circumstances without reservation
1B	Strong recommendation, moderate-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	RCTs with important limitations (inconsistent results, methodologic flaws, indirect, or imprecise) or exceptionally strong evidence from observational studies	Strong recommendation, can apply to most patients in most circumstances without reservation
1C	Strong recommendation, low-quality or very-low-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	Observational studies or case series	Strong recommendation but may change when higher quality evidence becomes available
2A	Weak recommendation, high-quality evidence	Benefits closely balanced with risks and burdens	RCTs without important limitations or overwhelming evidence from observational studies	Weak recommendation, best action may differ depending on circumstances or patients' or societal values
2B	Weak recommendation, moderate-quality evidence	Benefits closely balanced with risks and burdens	RCTs with important limitations (inconsistent results, methodologic flaws, indirect, or imprecise) or exceptionally strong evidence from observational studies	Weak recommendation, best action may differ depending on circumstances or patients' or societal values
2C	Weak recommendation, low-quality or very-low-quality evidence	Uncertainty in the estimates of benefits and risk, and burdens; Risk, benefit, and burdens may be closely balanced	Observational studies or case series	Very weak recommendations; Other alternatives may be reasonable

Modified from Guyatt G, Gutterman D, Baumann MH, Addrizzo-Harris D, Hylek EM, Phillips B, et al. Grading strength of recommendations and quality of evidence in clinical guidelines: Report from an American College of Chest Physicians task force. Chest 2006;129:174-81.

Clinical Algorithm(s)

An algorithm titled "Proposed algorithm for operative and endovascular management of patients with venous leg ulcers (VLU) based on involved anatomic venous system and presence of venous reflux or obstruction" is provided in the original guideline document.

Scope

Disease/Condition(s)

Venous leg ulcers (VLUs)

Guideline Category

Management

Prevention

Treatment

Clinical Specialty

Internal Medicine

Surgery

Intended Users

Physicians

Guideline Objective(s)

To provide recommendations on complete management of venous leg ulcers (VLUs) at all levels of care based on strength and quality of supporting evidence to guide specific recommendations

Target Population

Patients with or at risk for venous leg ulcers (VLUs)

Interventions and Practices Considered

1. Clinical evaluation

- Identification of medical conditions
- Wound measurement and documentation
- Wound culture if there are signs on infection
- Wound biopsy
- Laboratory evaluation for thrombophilia
- Arterial pulse examination and measurement of ankle-brachial index
- Microcirculation assessment (in selected cases)
- Venous duplex ultrasound
- Venous plethysmography
- Venous imaging (selective computed tomography venography, magnetic resonance venography, contrast venography, and/or intravascular ultrasound)
- Venous disease classification
- Venous procedural outcome assessment

2. Wound care

- Cleansing
- Surgical débridement (with local anesthesia)
- Other débridement methods (e.g., hydrosurgical, enzymatic, biologic)
- Management of cellulitis
- Antimicrobials
- Periulcer skin management
- Systemic antibiotics
- Adjuvant wound therapy

3. Compression

4. Operative/endovascular management

- Ablation of incompetent veins with compressive therapy
- Ablation of perforating veins with percutaneous techniques (e.g., ultrasound-guided sclerotherapy, endovenous thermal ablation)
- Autogenous venous bypass
- Endophlebectomy

- Individual valve repair
- Transposition or transplantation
- Autogenous valve substitutes
- Venous angioplasty and stent recanalization
- Open surgical bypass
- Adjunctive arteriovenous fistula

5. Ancillary measures

- Nutrition assessment
- Pentoxifylline or micronized purified flavonoid fraction
- Active exercise
- Balneotherapy

6. Primary prevention

- Compression
- Current evidence-based therapies for acute deep vein thrombosis (DVT)
- Patient and family education, regular exercise, leg elevation, skin care, weight control, and appropriate footwear

Note: The following were considered but not recommended: deep vein ligation, anti-inflammatories, adjunctive lymphatic drainage, ultraviolet light, prophylactic interventional therapies.

Major Outcomes Considered

- Anatomic success
- Venous hemodynamic success
- Procedure-related minor and major complications
- Impact on venous leg ulcer healing
- Pain reduction

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): Two systematic reviews were prepared to support the development of this guideline (see the "Availability of Companion Documents" field).

Search Strategy

With the assistance of an expert librarian, the systematic review authors designed and conducted an electronic search strategy, the details of which are available in appendices of the systematic reviews. The authors conducted a comprehensive search for randomized controlled trials (RCTs) and comparative observational studies from January 1990 to December 2013. The databases included in the search were Ovid Medline In-Process & Other Non-Indexed Citations, Ovid MEDLINE, Ovid EMBASE, Ovid Cochrane Central Register of Controlled Trials, Ovid Cochrane Database of Systematic Reviews, and Scopus. Controlled vocabulary supplemented with keywords was used to search for comparative studies of compression therapy for venous leg ulcers (VLUs). The authors also performed a secondary hand search of the reference lists of all included studies as well as from previously published systematic reviews on this topic.

Study Selection

References from the searches were uploaded to Distiller SR (Evidence Partners Inc, Ottawa, Ontario, Canada), an online application designed specifically for the screening and data extraction phases of a systematic review. Two reviewers, working independently, screened all titles and abstracts for eligibility. All references that were considered potentially relevant were retrieved in full text and again screened by two independent reviewers against the eligibility criteria. Disagreements were resolved by a third reviewer.

Two reviewers working independently extracted data from all eligible studies using a standardized form. Collected data included study description, methodologic quality assessment, and outcome data. These data were then collated, and any discrepancies were clarified by a third reviewer. The reviewers considered studies that included adults in any care setting who were described as having lower extremity ulcerations diagnosed as being due to venous disease, regardless of which method of diagnosis was used. Excluded were studies that included individuals with lower extremity ulcerations due to other etiologies (e.g., arterial, neuropathic, or vasculitis) and that those reported ulcers due to mixed etiologies and did not report outcome data separately for venous ulcers.

Refer to the systematic reviews for additional study selection information.

Number of Source Documents

Comparative Systematic Review and Meta-analysis of Compression Modalities for the Promotion of Venous Ulcer Healing and Reducing Ulcer Recurrence

The initial search revealed 778 citations, from which 309 were selected for full text retrieval and review. Of those articles excluded after full text screening, the reasons for exclusion were study design was not a controlled trial or comparative cohort (57), the study did not include patients with only venous ulcers (25), did not compare the interventions of interest (162), did not evaluate an outcome of interest (22), and could not be translated (5). The systematic review authors identified 38 eligible studies, which represented 36 unique studies in 34 published articles, two unpublished abstracts, and two systematic reviews (see Figure 1 in the systematic review [see the "Availability of Companion Documents" field]).

Systematic Review and Meta-analysis of Surgical Interventions Versus Conservative Therapy for Venous Ulcers

The initial search revealed 731 citations, from which 306 were selected for full text retrieval and review. Of those articles excluded after full text screening, 144 studies were excluded because the study design was not a controlled trial or comparative cohort, 30 did not include patients with only venous ulcers, 109 did not compare the interventions of interest, 6 did not evaluate an outcome of interest, and 4 could not be translated. The authors identified 13 eligible articles that represented 12 unique studies (see Figure 1 in the systematic review [see the "Availability of Companion Documents" field]). Eight articles reported results from seven randomized controlled trials (RCTs), three reported results from nonrandomized trials, and two reported results from historical comparative cohorts. Results were reported on 1451 ulcerated limbs (the number of patients were not available from all studies because some studies only reported the number of limbs).

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

See the "Rating Scheme for the Strength of the Recommendations" field.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): Two systematic reviews were prepared to support the development of this guideline (see the "Availability of Companion Documents" field).

Validity Assessment

Validity and methodologic quality was assessed using the Cochrane risk of bias tool to determine the following for randomized controlled trials (RCTs):

- How the randomization sequence was generated and concealed
- Whether the randomization successfully ensured no important differences between groups at baseline
- How blinding was achieved and which individuals were blinded
- How follow-up was assessed and reported
- How the analysis was reported

The systematic review authors used the Newcastle-Ottawa Scale to determine the following for cohort studies:

- Selection of study cohorts: how representative these cohorts were of patients of interest, whether adequate ascertainment of the exposures and outcomes at baseline was conducted
- Comparability of study cohorts by means of matching or statistical adjustment by key predictors of outcome
- Ascertainment of outcome: planning long enough follow-up to allow time for critical outcomes to develop, blinding the assessment of outcomes in both groups, etc.

Statistical Analysis

Results were grouped according to the types of interventions compared. Statistical pooling of outcome data was performed using Comprehensive Meta-Analysis 2 software (Biostat, Englewood, NJ). Because the reviewers anticipated significant heterogeneity between the studies given variable types of surgical interventions and variable types of compression, the reviewers presented all data using a random effects model. Sensitivity analyses were performed with poorly designed studies (with a high risk of biased results as determined by the validity assessment described above) removed. Subgroup analyses on outcomes in the following subgroups were also planned: ulcer size (<2 cm vs ≥2 cm), medial vs lateral ulcers, first-time ulcers vs recurrent ulcers, specific type of surgical intervention, and presence of deep venous system involvement vs superficial venous involvement alone. Unfortunately, too few studies reported separate outcomes for these variables, so many of these subgroup analyses were not performed.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The Venous Ulcer Guidelines Committee was organized through cooperation between the Society for Vascular Surgery (SVS) and the American Venous Forum (AVF). The Venous Ulcer Guidelines Committee was divided into six sub-committee sections each headed by a chair: diagnosis; compression; surgery/endovascular; wound care; ancillary; and prevention.

The overall committee then developed a series of key clinical questions to guide the overall approach for the guideline document: (1) What is the best treatment for active (clinical, etiology, anatomy, and pathophysiology classification [CEAP] C6) venous ulcer? (2) What is the best treatment for healed venous ulcer (CEAP C5)? (3) What is the best method for preventing recurrence of venous ulcers? and (4) Can progression from CEAP C4 to CEAP C6/C5 be prevented? The Venous Ulcer Guidelines Committee addressed the optimal approach to be used for their specific section from four general approaches: (1) de novo development, in which a completely novel recommendation is developed from a systematic and meta-analysis review of the literature; (2) build on existing guidelines with a complementary full-literature search update; (3) adapt guidelines from existing guidelines; and (4) total adoption of existing guidelines. The need for a systematic and meta-analysis review was determined by each section team and then agreed on by the entire committee. Each section was categorized by the type of guideline development required. All guidelines were developed by building on existing guidelines with a complementary literature search by the section sub-committee.

In this process of guideline development for venous leg ulcers (VLUs), the Venous Ulcer Guidelines Committee also reviewed prior published consensus documents and the AVF report from the 2006 Venous Summit and the 2009 Pacific Vascular Symposium, whose purpose was to reduce the incidence of venous ulcer during the next decade by 50%. In a previous systematic review of recently published venous ulcer guidelines, 14 venous ulcer guidelines were identified worldwide. This review showed that there was a high degree of agreement among the 14 VLU guidelines on recommendations for compression (72%), dressings (72%), pentoxifylline (73%), prevention of recurrence by below-knee stockings (70%), and surgery (82%). There was a low proportion of agreement in the areas of diagnosis, clinical evaluation, and venous Doppler and duplex

ultrasound; in elements of wound care: measurement of the wound, washing of the wound, débridement, and specific type of wound dressing; and finally in adjunctive measures: the use of skin grafts and physical therapy to promote ankle mobility with enhancement of the calf muscle pump. Several areas of "controversy" were identified that had not been particularly addressed in previous guidelines: new innovative, less invasive VLU therapies; the role of iliac obstruction and occlusion with the need for diagnosis by intravascular ultrasound and subsequent monitoring of stenting by this technique; when and by what methods to treat perforators; the need for physical therapy to promote ankle mobility and function of the calf muscle pump; the role of advanced dressings; and preventing progression to VLU. These areas received special attention in review for the current guidelines.

The surgery/endovascular and compression sections were selected for a de novo development of specific guideline recommendations based on several of these key questions. For additional systematic review involving these critical areas, the Venous Ulcer Guidelines Committee commissioned an independent group of researchers to conduct two systematic reviews to evaluate the effectiveness of different compression strategies and endovascular and open surgical approaches. The Committee helped develop a priori the protocols of these reviews in terms of outcome selection and criteria for including studies with additional analysis by the Knowledge and Evaluations Research Unit at the Mayo Clinic (Rochester, Minn).

Through an iterative process, the committee developed guidelines based on the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system (see the "Rating Scheme for the Strength of the Recommendations" field). The strength of the recommendations is related to (1) the quality of evidence around that recommendation, (2) harm/benefit ratio of the therapy (e.g., minimally invasive intervention with few morbid events and a possible effect), and (3) patient preference. Every effort has been made by the committee to make the process of assigning the strength of the particular recommendation as transparent as possible. By the GRADE system, the strength of the recommendation or the extent to which one can be confident that adherence to the recommendation will do more good than harm was divided into [1] strong (the Committee recommends) and [2] weak (the Committee suggests), with [1] favoring benefit over harm and [2] with benefits closely balanced by the risk. The "quality of evidence" or the extent to which confidence in an estimate of effect is sufficient to support a particular recommendation was graded [A], [B], or [C] by standard evidence-based methodologic criteria. It is well recognized that there may not be studies of the highest evidentiary value for the diagnosis and management of VLUs. When there were no comparable alternatives to a recommendation or evidence was lacking, the Venous Ulcer Guidelines Committee relied on case series supplemented by the best opinion of a panel of experts, and the recommendation was labeled [BEST PRACTICE]. Such recommendations were not graded but deemed by the guideline developers to be necessary to provide a comprehensive guideline that encompasses all the details needed for providing care for patients with venous ulcers. Independent review of GRADE assignments made by the Venous Ulcer Guidelines Committee was also performed by the Knowledge and Evaluations Research Unit at the Mayo Clinic (Rochester, Minn) to corroborate proper strength of evidence and quality of evidence for each guideline.

Rating Scheme for the Strength of the Recommendations

Grading of Recommendations Assessment, Development and Evaluation (GRADE) Recommendations Based on Level of Evidence

Grade	Description of Recommendation	Benefit vs. Risk	Methodologic Quality of Supporting Evidence	Implications
1A	Strong recommendation, high-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	Randomized controlled trials (RCTs) without important limitations or overwhelming evidence from observational studies	Strong recommendation, can apply to most patients in most circumstances without reservation
1B	Strong recommendation, moderate-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	RCTs with important limitations (inconsistent results, methodologic flaws, indirect, or imprecise) or exceptionally strong evidence from observational studies	Strong recommendation, can apply to most patients in most circumstances without reservation
1C	Strong recommendation, low-quality or very-low-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	Observational studies or case series	Strong recommendation but may change when higher quality evidence becomes available
2A	Weak recommendation, high-quality evidence	Benefits closely balanced with risks and burdens	RCTs without important limitations or overwhelming evidence from observational studies	Weak recommendation, best action may differ depending on circumstances or patients' or societal

Grade	Description of Recommendation	Benefit vs. Risk	Methodologic Quality of Supporting Evidence	Implications
2B	Weak recommendation, moderate-quality evidence	Benefits closely balanced with risks and burdens	RCTs with important limitations (inconsistent results, methodologic flaws, indirect, or imprecise) or exceptionally strong evidence from observational studies	Weak recommendation, best action may differ depending on circumstances or patients' or societal values
2C	Weak recommendation, low-quality or very-low-quality evidence	Uncertainty in the estimates of benefits and risk, and burdens; Risk, benefit, and burdens may be closely balanced	Observational studies or case series	Very weak recommendations; Other alternatives may be reasonable

Modified from Guyatt G, Gutterman D, Baumann MH, Addrizzo-Harris D, Hylek EM, Phillips B, et al. Grading strength of recommendations and quality of evidence in clinical guidelines: Report from an American College of Chest Physicians task force. Chest 2006;129:174-81.

Cost Analysis

The guideline developers reviewed published cost analyses.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

The final document was reviewed by the chairman and vice chairman of the Venous Ulcer Guidelines Committee and remitted to the entire committee for concurrence. Additional independent review was obtained from selected reviewers representing multiple medical specialties vested in venous ulcer management. The final document was then reviewed and approved by the Society for Vascular Surgery (SVS) Document Oversight Committee and approved by the Executive Committees of the SVS and American Venous Forum (AVF).

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Improved wound healing
- There is some evidence to support a beneficial impact of increased physical activity, improved mobility, and foot exercises on lowering recurrence.

Potential Harms

- Compression of a limb with significant arterial disease could compromise arterial perfusion and potentially result in adverse ischemic sequelae. In a survey study, nearly one third of general surgery consultants surveyed reported that they had encountered ulcers or necrosis

as the direct result of compression treatment.

- Contact dermatitis related to the dressings and other products used to treat venous leg ulcers (VLUs) is frequent.
- In patients with diabetes, renal insufficiency, or other diseases that cause vascular calcification, tibial vessels at the ankle become noncompressible, leading to a false elevation of the ankle pressure and ankle-brachial index.
- The risks of open procedures, which specifically include infection, difficulty in healing of incisions required for treatment, increased local trauma, hematoma formation, and need for general anesthesia, set open operations apart from the less invasive percutaneous methods.
- Specific footwear and risk of VLU has not been tested, but caution should be exercised in those with C3 or higher clinical class venous disease.

Qualifying Statements

Qualifying Statements

The Society for Vascular Surgery/American Venous Forum (SVS/AVF) Evidence-Based Clinical Practice Guidelines for Management of Venous Leg Ulcers is the end result of a programmatic initiative by the AVF "to reduce the incidence of venous ulcer 50% over the next decade" combined with the need for clinical practice guidelines for venous leg ulcers (VLUs), as recognized by the SVS Document Oversight Committee. With the primary target audience for these guidelines, specialists who treat VLUs, the current guidelines attempt to update as well as to address gaps in prior VLU guidelines. A recent systematic analysis of existing VLU guidelines demonstrated concordance in certain areas but significant management gaps in others, such as advanced wound therapies, role of thermal ablation of superficial venous disease, valve reconstruction, and treatment of outflow obstruction by stenting, all of which were not addressed in previous guideline documents. Toward that end, formal new systematic review and meta-analyses were performed for two areas, compression and surgical/endovascular treatments.

The current SVS/AVF clinical practice guidelines are based on the best level of evidence currently available for a recommendation. The strength of a recommendation for a specific guideline is tempered by the quality of evidence supporting that recommendation. The SVS/AVF Joint Clinical Practice Guidelines Committee has reviewed the grading of recommendations within each sub-committee and as an overall group with an eye toward a critical assessment. Overall, the evidence level for venous ulcer management is mostly of moderate strength, and as a consequence, most recommendations as a whole achieve lower grades, Grade 2B (18.6%) and Grade 2C (53.3%); in some instances, the recommendations may not be graded and are designated Best Practice (10.7%). Parenthetically it should be noted that the current American College of Chest Physicians guidelines for antithrombotic therapy and prevention of thrombosis contain no Grade 1A recommendations. This observation points to the need for more well-done randomized controlled studies on the management of VLUs. Whereas the current VLU guidelines attempt to cover the state of evidence as it exists today, as more evidence comes to fruition, updates and modifications will be required on an ongoing basis, so that these VLU guidelines become "living documents." The treatment of VLU currently is hampered by a siloed approach, that is, just focusing on ulcer healing or ulcer recurrence rather than on the continuum of care. For expressing and assessing cost/resource utilization as well as quality of outcomes, how long the skin remains in an ulcer-free state (ulcer-free interval), as expressed by the percentage of the follow-up period that the skin is ulcer free, is a more valuable metric.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Clinical Algorithm

Mobile Device Resources

Slide Presentation

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

O'Donnell TF Jr, Passman MA, Marston WA, Ennis WJ, Dalsing M, Kistner RL, Lurie F, Henke PK, Gloviczki ML, Eklaiff BG, Stoughton J, Raju S, Shortell CK, Raffetto JD, Partsch H, Pounds LC, Cummings ME, Gillespie DL, McLafferty RB, Murad MH, Wakefield TW, Gloviczki P, Society for Vascular Surgery, American Venous Forum. Management of venous leg ulcers: clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. J Vasc Surg. 2014 Aug;60(2 Suppl):3S-59S. [547 references] [PubMed](#)

Adaptation

Not applicable: The guideline was not adapted from another source.

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Guideline Developer(s)

American Venous Forum - Disease Specific Society

Society for Vascular Surgery - Medical Specialty Society

Source(s) of Funding

Society for Vascular Surgery

Guideline Committee

Society for Vascular Surgery (SVS)/American Venous Forum (AVF) Joint Clinical Practice Guidelines Committee—Venous Leg Ulcer

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Financial Disclosures/Conflicts of Interest

Author conflict of interest: none

Guideline Endorser(s)

American College of Phlebology - Medical Specialty Society

Union Internationale de Phlébologie - Professional Association

Guideline Status

This the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the [Journal of Vascular Surgery Web site](#) .

Availability of Companion Documents

The following are available:

- Mauck KF, Asi N, Elraiyah TA, Undavalli C, Nabhan M, Altayar O, Sonbol MB, Prokop LJ, Murad MH. Comparative systematic review and meta-analysis of compression modalities for the promotion of venous ulcer healing and reducing ulcer recurrence. *J Vasc Surg*. 2014 Aug;60(2 Suppl):71S-90S. Available from the [Journal of Vascular Surgery Web site](#) .
- Mauck KF, Asi N, Undavalli C, Elraiyah TA, Nabhan M, Altayar O, Sonbol MB, Prokop LJ, Murad MH. Systematic review and meta-analysis of surgical interventions versus conservative therapy for venous ulcers. *J Vasc Surg*. 2014 Aug;60(2 Suppl):60S-70S. Available from the [Journal of Vascular Surgery Web site](#) .
- Management of venous leg ulcers: clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. Slide set. Chicago (IL): Society for Vascular Surgery; 2014 Aug. 72 p. Available from the [Society for Vascular Surgery \(SVS\) Web site](#) .

A clinical practice guidelines app is available from the [SVS Web site](#) .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on November 18, 2015. The information was verified by the guideline developer on December 16, 2015. This summary was updated by ECRI Institute on February 15, 2017 following the U.S. Food and Drug Administration advisory on general anesthetic and sedation drugs.

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